37 C.F.R. §§ 1.136(a) and 1.17(a)(3). With the extension, the time for response is extended up to and including November 28, 2004.

REMARKS

Each of the Examiner's rejections is addressed below.

Claim Rejections

Claims 31, 33 and 34 are pending in this application. The claims are directed to a method of treating human cancers or tumors by administering to a patient a composition comprising a recombinant IFN-β polypeptide produced by a DNA sequence that is operatively linked to an expression control sequence. As the Examiner has requested, applicant has attached a copy of the now pending claims as Appendix A.

Claims 31, 33 and 34 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claim 37 of co-pending patent application 08/253,843 and claims 31, 33 and 34 of co-pending patent application 08/449,930. Applicant agrees to file one or more terminal disclaimers or to cancel or to amend the claims, as appropriate, in this or the co-pending applications to obviate the obviousness-type double patenting rejections upon allowance of any of the conflicting claims.

Claims 31 and 34 stand rejected under 35 U.S.C. § 102(g) as anticipated by Sugano et al. (U.S. Patent 5,514,567) or Sugano et al. (U.S. Patent 5,326,859). According to the Examiner, each Sugano patent discloses "as much about treatment of human cancers

or tumors as does the instant application." Applicant traverses. Neither of the Sugano patents is 35 U.S.C. § 102(g) prior art to pending claims 31, 33 and 34.

Section 2138 of the MPEP makes plain that an issued United States patent cannot form the basis of a rejection under 35 U.S.C. § 102(g):

> "To qualify as prior art under 35 U.S.C. 102(g), . . . there must be evidence that the subject matter was actually reduced to practice, in that conception alone is not sufficient. See *Kimberly-Clark*, 745 F.2d at 1445, 223 USPQ at 607. While filing of an application for patent is a constructive reduction to practice, the filing of an application does not itself provide evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an *ex parte* rejection under 35 U.S.C. 102(g)."

Accordingly, neither Sugano patent is 35 U.S.C. § 102(g) prior art to the pending claims.* Applicant requests reconsideration and withdrawal of this rejection.

* The Sugano patents also are not prior art under 35 U.S.C. § 102(e). See Applicants July 14, 2003 Reply to Office Action.

For all the above reasons, reconsideration and allowance of the pending claims is requested.

Respectfully submitted,

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APPENDIX A

31. A method for treating human cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising:

1) a recombinant polypeptide produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:

(a) DNA sequences which hybridize to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322-(Pst)/HFIF7 (DSM 1793), and which code for a polypeptide displaying antiviral activity, and

(b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);

said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule; and

2) a pharmaceutically acceptable carrier.

33. The method according to claim 31, wherein said DNA sequence is selected from DNA sequences of the formulae:

ATGACCAACAAGTGTCTCCTCCAAATTGCTCTCCTGTTGTGCTTCTCCACTACAGCT
CTTTCCATGAGCTACAACTTGCTTGGATTCCTACAAAGAAGCAGCAATTTTCAGTGT
CAGAAGCTCCTGTGGCAATTGAATGGGAGGCTTGAATACTGCCTCAAGGACAGGATG
AACTTTGACATCCCTGAGGAGATTAAGCAGCTGCAGCAGTTCCAGAAGGAGGACGCC
GCATTGACCATCTATGAGATGCTCCAGAACATCTTTGCTATTTTCAGACAAGATTCA

TCTAGCACTGGCTGGAATGAGACTATTGTTGAGAACCTCCTGGCTAATGTCTATCAT
CAGATAAACCATCTGAAGACAGTCCTGGAAGAAAAACTGGAGAAAGAAGATTTCACC
AGGGGAAAACTCATGAGCAGTCTGCACCTGAAAAGATATTATGGGAGGATTCTGCAT
TACCTGAAGGCCAAGGAGTACAGTCACTGTGCCTGGACCATAGTCAGAGTGGAAATC
CTAAGGAACTTTTACTTCATTAACAGACTTACAGGTTACCTCCGAAAC, and ATG
AGCTACAACTTGCTTGGATTCCTACAAAGAAGCAGCAATTTTCAGTGTCAGAAGCTC
CTGTGGCAATTGAATGGGAGGCTTGAATACTGCCTCAAGGACAGGATGAACTTTGAC
ATCCCTGAGGAGATTAAGCAGCTGCAGCAGTTCCAGAAGGAGGACGCCGCATTGACC
ATCTATGAGATGCTCCAGAACATCTTTGCTATTTTCAGACAAGATTCATCTAGCACT
GGCTGGAATGAGACTATTGTTGAGAACCTCCTGGCTAATGTCTATCATCAGATAAAC
CATCTGAAGACAGTCCTGGAAGAAAAACTGGAGAAAGAAGATTTCACCAGGGGAAAA
CTCATGAGCAGTCTGCACCTGAAAAGATATTATGGGAGGATTCTGCATTACCTGAAG
GCCAAGGAGTACAGTCACTGTGCCTGGACCATAGTCAGAGTGGAAATCCTAAGGAAC
TTTTACTTCATTAACAGACTTACAGGTTACCTCCGAAAC.

34. The method according to claim 31 wherein the polypeptide is selected from polypeptides of the formulae: Met-Thr-Asn-Lys-Cys-Leu-Leu-Gln-Ile-Ala-Leu-Leu-Leu-Cys-Phe-Ser-Thr-Thr-Ala-Leu-Ser-Met-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-Gln-Cys-Gln-Lys-Leu-Leu-Trp-Gln-Leu-Asn-Gly-Arg-Leu-Glu-Tyr-Cys-Leu-Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-Glu-Ile-Lys-Gln-Leu-Gln-Gln-Phe-Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn, and Met-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-Gln-Cys-Gln-Lys-Leu-Leu-Trp-Gln-Leu-Asn-Gly-Arg-Leu-Glu-Tyr-Cys-Leu-Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-Glu-Ile-Lys-Gln-Leu-Gln-Gln-Phe-

Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn.